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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,759	10/12/2004	Chikage Mataki	260187US0PCT	7309

22850 7590 09/11/2007

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER
O DELL, DAVID K

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
09/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/510,759	MATAKI ET AL.	
	Examiner	Art Unit	
	David K. O'Dell	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 Augusut 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *11-15 and 26-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 16-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5 July 2006 & 12 October 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-60 are pending, in the current application. Claims 11-15, 26-60 are withdrawn from consideration. Claims 11-15, 26-30, were not drawn to the elected invention since the elected invention is a compound and independent claims 11 and 26 read on "a gene therapy facillitater[sic] comprising.....administering" which cannot be a compound unless the applicant is suggesting that matter can be composed of actions such as administering. Claims 1-10, 16-25 are under examination.

Priority

2. This application is a national stage of PCT/JP03/04602 filed April 11, 2003, which claims benefit of U.S. Provisional Applications: 60/371,675 filed March 12, 2002 and 60/412,571 filed September 23, 2002, both of these provisional applications are filed in a language other than English. An English translation of the non-English language provisional application and a statement that the translation is accurate must be filed in provisional application Nos. 60/371,675 & 60/412,571. See 37 CFR 1.78(a)(5). The English translation and a statement that the translation is accurate required by 37 CFR 1.78(a)(5) is missing. Accordingly, applicant must supply 1) the missing English translation and a statement that the translation is accurate in provisional application Nos. 60/371,675 & 60/412,571 and 2) in the present application, a confirmation that the translation and statement were filed in the provisional application. If 1) and 2) are not filed (or the benefit claim withdrawn by the filing of an amendment or Supplemental Application Data Sheet) prior to the expiration of the time period set in this Office action, the present application will be abandoned. See 37 CFR 1.78(a)(5)(iv).

Response to Restriction/Election

3. Applicant's election with traverse of Group I and the species of example 10, in the reply filed on August 13, 2007 is acknowledged. The traversal is on the ground(s) that it was improper because the examiner failed to show a lack of unity and that no search burden exists. Search burden is not a consideration under PCT Rule 13.1, but rather a special technical feature is the controlling factor. While the applicant has alleged that the examiner has failed to provide evidence that this special technical feature is not present, despite the fact that the examiner clearly showed the lack of novelty of the core, at applicant's behest, the examiner submits that U.S. Patent 6,395,753 shows that the compounds are in fact not novel, thus providing ample evidence that no special technical feature is present. This application contains claims drawn to a nonelected invention with traverse. A complete reply to this action must include a cancellation of nonelected claims or other appropriate action.

Under examination:

Group I, claims 1-10, 16-25 drawn to compounds and compositions with a pyridyl-piperidinyl-pyridyl core where in formula 1 claim 1, l is 1; m is 0, X is NR_4, R_4 is phenyl, W1 = W2 = N, shown as structure **I** figure 1, classified in class 546, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

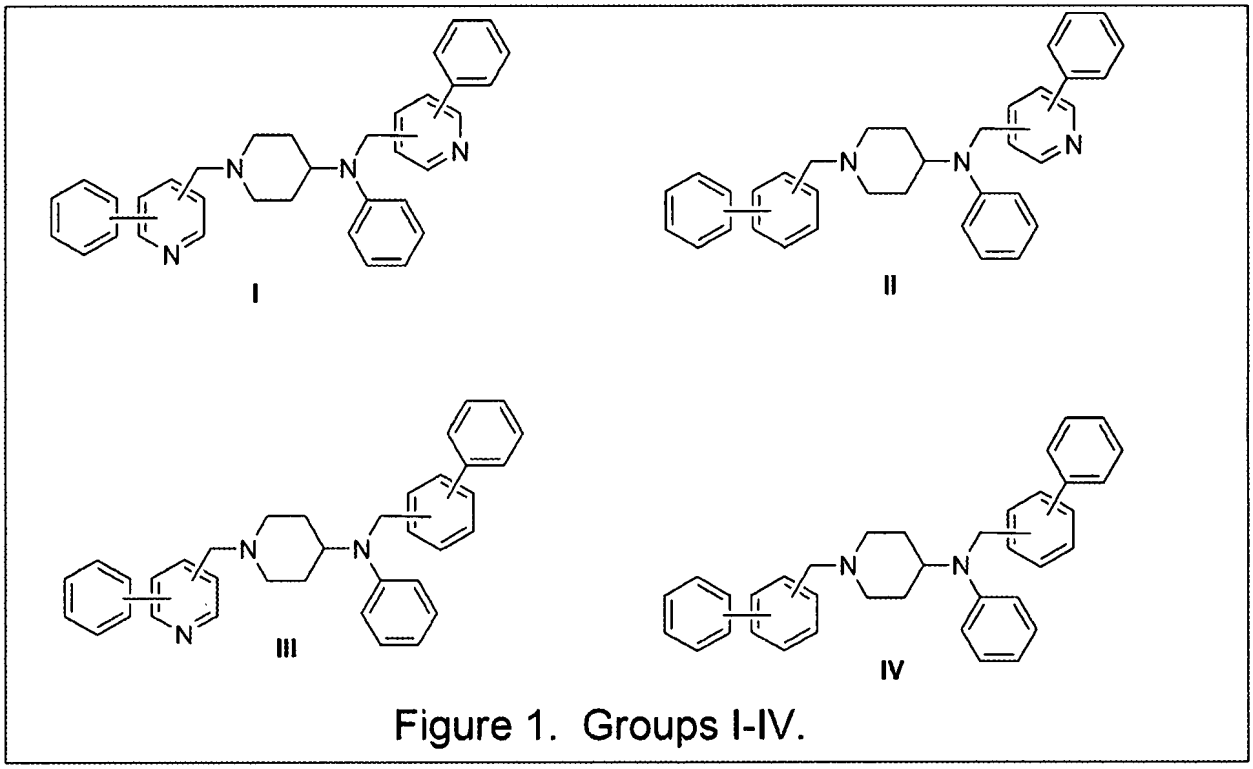


Figure 1. Groups I-IV.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10, 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. Claims 1-5, 6-10, ~~11-15~~, 16-20, 21-25, 26-30 are drawn to compounds and compositions with the recitation of functional language "~~gene therapy facilitater~~" [sic], "medicine for treating cancer", "histone deacetylase inhibitor", and are drawn to the same materials, and based on the election following the restriction requirement these appear to be compound claims not method claims. If these are in fact compound claims, the functional language should be removed. See *Union Oil Co. of California v. Atlantic Richfield*

Co. 54 USPQ2d 1227 where "composition claims cannot, as the appellant refiners argue, embrace only certain uses of that composition. (citing *In Re Spada*) Otherwise these composition claims would mutate into method claims." If the applicant has intended to claim a method of treatment, the wrong group was chosen, however a method of treating commensurate in scope with the allowed compound claims may be rejoined if the compounds become allowable. The claims will be examined to the extent they cover compounds and compositions, not as they relate to any method of treating, facilitating or inhibition.

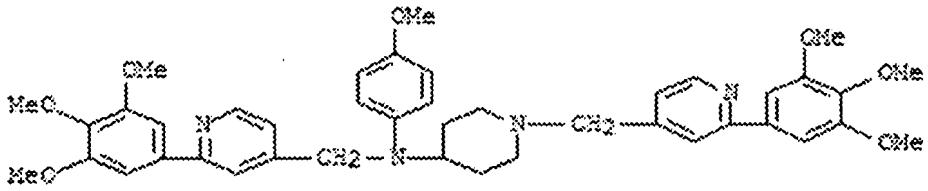
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-10, 16-25 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 2003020703. This document reveals the elected species of example 10,

RN 427886-37-1 CAPLUS
CN 4-Pyridinemethanamine, N-(4-methoxyphenyl)-2-(3,4,5-trimethoxyphenyl)-N-[1-[[2-(3,4,5-trimethoxyphenyl)-4-pyridinyl]methyl]-4-piperidinyl]-, trihydrochloride (9CI) (CA INDEX NAME)

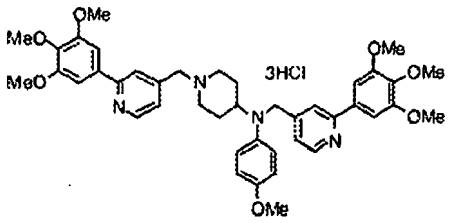


● 3 HCl

this compound is on pg. 60:

WO 03/020703 PCT/JP02/08650

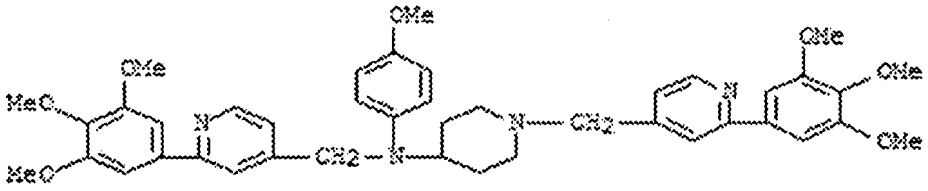
5－トリメトキシフェニル）ピリジン－4－イル］メチル］ピペリジン・3塩酸塩の合成：



as well as the other species of the instant application and a couple of hundred or so anticipatory compounds, and compositions.

6. Claims 1-10, 16-25 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent 6,395,753. This document reveals the elected species of example 10,

RN 427886-37-1 CAPLUS
CN 4-Pyridinemethanamine, N-(4-methoxyphenyl)-2-(3,4,5-trimethoxyphenyl)-N-[1-[[2-(3,4,5-trimethoxyphenyl)-4-pyridinyl]methyl]-4-piperidinyl]-, trihydrochloride (9CI) (CA INDEX NAME)

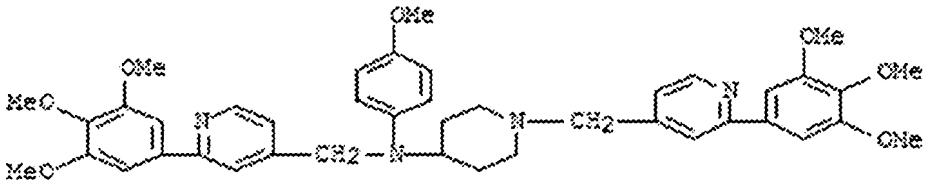


●3 HCl

as example 10 column 44, as well as the other species of the instant application and a couple of hundred or so anticipatory compounds, and compositions..

7. Claims 1-10, 16-25 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent 6,498,169. This document reveals the elected species of example 10,

RN 427886-37-1 CAPLUS
CN 4-Pyridinemethanamine, N-(4-methoxyphenyl)-2-(3,4,5-trimethoxyphenyl)-N-[1-[[2-(3,4,5-trimethoxyphenyl)-4-pyridinyl]methyl]-4-piperidinyl]-, trihydrochloride (9CI) (CA INDEX NAME)



●3 HCl

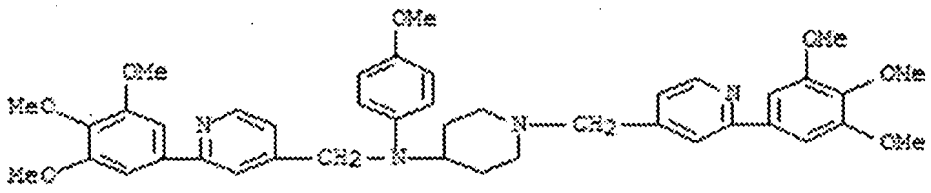
as example 10 column 47, as well as the other species of the instant application and a couple of hundred or so anticipatory compounds, and compositions.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-10, 16-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,395,753. This document reveals the elected species of example 10,

RN 427886-37-1 CAPLUS
CN 4-Pyridinemethanamine, N-(4-methoxyphenyl)-2-(3,4,5-trimethoxyphenyl)-N-[1-[[2-(3,4,5-trimethoxyphenyl)-4-pyridinyl]methyl]-4-piperidinyl]-, trihydrochloride (9CI) (CA INDEX NAME)



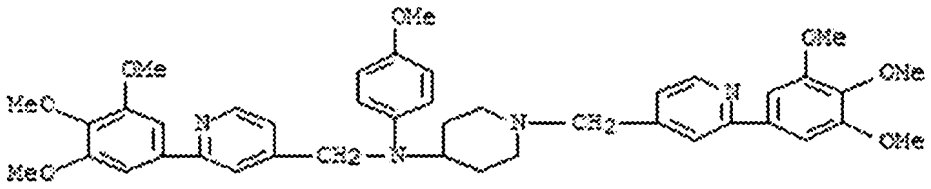
● 3 HCl

as example 10 column 44, as well as the other species of the instant application and a couple of hundred or so anticipatory compounds, and compositions.

The applied reference has a common assignee, and some inventors in common with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

9. Claims 1-10, 16-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,498,169. This document reveals the elected species of example 10,

RN 427886-37-1 CAPLUS
CN 4-Pyridinemethanamine, N-(4-methoxyphenyl)-2-(3,4,5-trimethoxyphenyl)-N-[1-[[2-(3,4,5-trimethoxyphenyl)-4-pyridinyl]methyl]-4-piperidinyl]-, trihydrochloride (9CI) (CA INDEX NAME)



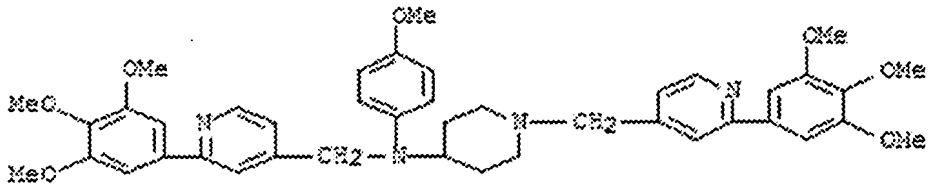
● 3 HCl

as example 10 column 47, as well as the other species of the instant application and a couple of hundred or so anticipatory compounds, and compositions.

The applied reference has a common assignee, and some inventors in common with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

10. Claims 1-10, 16-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pre-Grant Publication US 2004/00101417 A1. This document reveals the elected species of example 10,

RN 427666-97-1 CAPLUS
CN 4-Pyridinemethanamine, N-(4-methoxyphenyl)-2-(3,4,5-trimethoxyphenyl)-N-[1-[[2-(3,4,5-trimethoxyphenyl)-4-pyridinyl]methyl]-4-piperidinyl]-, trihydrochloride (9CI) (CA INDEX NAME)



● 3 HCl

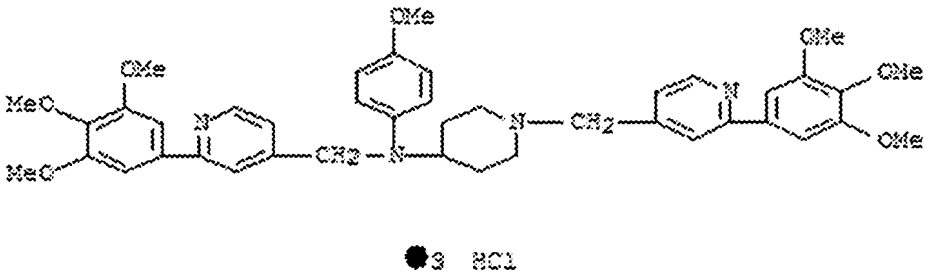
as example 10 page 27, as well as the other species of the instant application and a couple of hundred or so anticipatory compounds, and compositions.

The applied reference has a common assignee, and some inventors in common with the instant application. Based upon the earlier effective U.S. filing date of the reference, it

constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

11. Claims 1-10, 16-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6, 605,620. This document reveals the elected species of example 10,

RN 427886-37-1 CAPLUS
CN 4-Pyridinemethanamine, N-(4-methoxyphenyl)-2-(3,4,5-trimethoxyphenyl)-N-[1-[[2-(3,4,5-trimethoxyphenyl)-4-pyridinyl]methyl]-4-piperidinyl]-, trihydrochloride (9CI) (CA INDEX NAME)

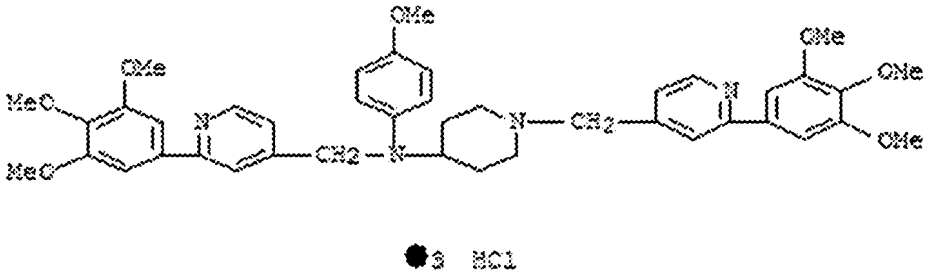


as example 10 column 52, as well as the other species of the instant application and a couple of hundred or so anticipatory compounds, and compositions.

The applied reference has a common assignee, and some inventors in common with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

12. Claims 1-10, 16-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6, 867,221. This document reveals the elected species of example 10,

RN 427886-37-1 CAPLUS
CN 4-Pyridinemethanamine, N-(4-methoxyphenyl)-2-(3,4,5-trimethoxyphenyl)-N-[1-[[2-(3,4,5-trimethoxyphenyl)-4-pyridinyl]methyl]-4-piperidinyl]-, trihydrochloride (9CI) (CA INDEX NAME)



● 3 HCl

as example 10 page 27, as well as the other species of the instant application and a couple of hundred or so anticipatory compounds, and compositions.

The applied reference has a common assignee, and some inventors in common with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Please NOTE: ALL of these applied 102(e) references claim priority to application 09/941,684 which reveals the elected compound as example 10 on pg. 46. The effective 102(e) date is August 30, 2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-10, 16-25 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to "medicines for treating cancer', "histone deacetylase inhibitor", and "pharmaceutical" compositions, however no compound has ever been found to treat cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "silver bullet" is contrary to our present understanding of oncology. Simone, Oncology: Introduction, Cecil Textbook of Medicine, 20th Edition, Vol. 1, pp. 1004-1010, 1996, states that, "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study' (see the enclosed article, page 1004). A 'disease caused by proliferation of tumor cell' is anything that is caused by abnormal tissue growth. That can be growth by cellular proliferation more rapidly than normal, or continued growth after the stimulus that initiated the new growth has ceased, or lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Different types of cancers affect different organs and have different methods of growth and harm to the body. Also see In re Buting, 163 USPQ 689 (CCPA 1969), wherein 'evidence involving a single compound and two types of

cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers'. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers. The ideal chemotherapeutic drug would target and destroy only cancer cells without adverse effects or toxicities on normal cells. Unfortunately, no such drug exists; there is a narrow therapeutic index between cell kill of cancer cells and that of normal cells. Successful treatment of cancer requires elimination of all cancer cells, whether at the primary site, extended to local-regional areas, or metastatic to other regions of the body. The major modalities of therapy are surgery and radiotherapy (for local and local-regional disease) and chemotherapy (for systemic sites). For example, regarding the treatment of leukemia, The Merck Manual (online edition) states, that "Treatment programs and clinical situations are complex". Dosage regimen is dependent on several risk factors and the contribution of each active ingredient of a multidrug combination therapy is complex and unclear. Similarly, Myelodysplastic syndrome (MDS) is characterized by clonal proliferation of hematopoietic cells, including erythroid, myeloid, and megakaryocytic forms and its incidence is unknown and further, there is no established treatment. Several growth factors and their receptors have been associated with glioma and the treatment depends on the pathology and location and is often multimodal. Cell line data for cancer drugs is well-known to be unpredictive of treatment, even animal data is not predictive see Trisha Gura "CANCER MODELS: Systems for Identifying New Drugs Are Often Faulty" Science 7 November 1997: Vol. 278. no. 5340, pp. 1041 – 1042:

"Indeed, since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models, but only 39 that are used exclusively for chemotherapy, as opposed to supportive care, have won approval from the U.S. Food and Drug Administration. "**The fundamental problem in drug discovery for cancer is that the model systems are not predictive at all**," says Alan Oliff, executive director for cancer research at Merck Research Laboratories in West Point, Pennsylvania."

Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the "pharmaceutical" use of the instant compounds. Moreover the specification does not seem disclose exactly what "histone deacetylase inhibition" actually is, much less any data indicating that any of the disclosed compounds are involved in its inhibition. Where is such data?

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13B. Claims 1-10, 16-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,395, 753. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims although somewhat narrower are overlapping in scope with those of the '753 patent, and cover the same compounds.

14. Claims 1-10, 16-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of 1-14 U.S. Patent No. 6,498,169. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims although somewhat narrower are overlapping in scope with those of the '169 patent, and cover the same compounds and compositions.

15. Claims 1-10, 16-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2,4,5 of U.S. Patent No. 6,605,620. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims cover genera, species, and compositions that are those species of the '620 patent.

16. Claims 1-10, 16-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,867,221. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims although somewhat narrower are overlapping in scope with those of the '221 patent, and cover the same compounds.

Specification

17. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested:

4-[N-[[(3,4,5-trimethoxyphenyl)pyridinyl]methyl]amino] –1-[[(3,4,5 -trimethoxyphenyl)pyridinyl]methyl]piperidines

Removal of the reference to cancer is required.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571) 272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Primary examiner, Rita Desai can be reached on (571)272-0684. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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D.K.O.

RITA DESAI
PRIMARY EXAMINER
8/31/07